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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,011	10/24/2003	Kenji Nakajima	Q78108	8536

23373 7590 10/26/2006
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EXAMINER

LUM, LEON YUN BON

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/692,011

Applicant(s)

NAKAJIMA, KENJI

Examiner

Leon Y. Lum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1,4,7,10 and 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,6 and 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/17/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed August 17, 2006 is acknowledged and has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 2-3, 5-6, 8-9, and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al (US 6,716,629 B2) in view of Clark et al (US 5,358,691).

Hess et al reference teaches the step of providing a platen (biochemical analysis unit; base plate) with an array of through-holes traversing the platen, the through-holes having a three-dimensional hydrophilic scaffold placed therein (i.e. porous adsorptive

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regions comprising holes filled with a porous material), and wherein the scaffold is activated to couple biological materials within the holes (i.e. bound receptors). See column 13, line 65 to column 14, line 3; and column 20, lines 45-62. In addition, Hess et al teach that platen can be used to screen for ligands by affinity (i.e. performing a specific binding detection process) by performing the step of applying pressure across the platen to create a flow of sample through the array of through-holes, where the sample is a second set of reagents that can react with reagents already loaded into the through-holes (i.e. forcibly causing a ligand to flow through the holes; ligand subject to specific binding with bound receptors). See column 35, lines 32-42; and column 28, lines 16-22. Furthermore, Hess et al teach that specific binding can be detected by applying a radiolabeled sample protein to an array of 100,000 different proteins in the platen, applying a wash step, and then detecting the presence of radiolabeled protein by a phosphor-imaging system (i.e. detecting the receptor by the utilization of a labeling substance; labeled receptor). See column 55, line 64 to column 56, line 7. Hess et al also teach that all through-holes can be loaded (i.e. through each of the holes). See column 7, lines 14-15.

However, Hess et al fail to teach the step of performing a bubble removing or dissolving process during the flowing of the liquid.

Clark et al reference teaches the step of automatically flushing bubbles out of a fluidics system, in order to prevent the presence of air bubbles from affecting the precision and accuracy of the dispenser. See column 21, lines 7-48.

It would have been obvious to one of ordinary skill in the art to modify the method of Hess et al with the step of automatically flushing bubbles out of the fluidics system, as taught by Clark et al, in order to prevent the presence of air bubbles from affecting the precision and accuracy of the dispenser. The advantage of providing more accurate dispensing of solution provides the motivation to combine the bubble-extracting step of Clark et al in the method of Hess et al. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in including the bubble extracting step of Clark et al in the method of Hess et al, since Hess et al teach the step of dispensing fluid into an array, and the bubble extracting process of Clark et al would provide a more effective way of dispensing the fluid.

With respect to claims 11-12, Hess et al teach that nucleic acids can be labeled with an enzyme (i.e. auxiliary substance-bound receptor) such as horseradish peroxidase and then incubated with a substrate that produces a luminescent, fluorescent, or chromogenic signal upon reaction with the enzyme following binding and washing steps (i.e. causing a labeling substance to bind to the auxiliary substance, and detecting the auxiliary substance bound receptor by utilization of the labeling substance). See column 36, lines 2-9.

Response to Arguments

5. Applicant's arguments in the response filed on August 17, 2006 traverse the Examiner's obviousness rejections of the previous Office Action. Applicant's arguments

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center on the allegation that there is no motivation to combine Hess and Clark references. See page 3, 1st full paragraph. Applicant's first rationale is that since Clark teaches the flushing of bubbles out of a syringe, this step cannot be applied to the pressure system of Hess. Specifically, Applicant contends: "Hess does not disclose that bubbles are formed during the application of pressure or any problems associated with the formation of bubbles. In addition, the disclosure relied upon by the Examiner relates to the application of pressure and not to the use of a syringe." See page 4, 2nd paragraph. In addition, Applicant argues that the purpose for removing bubbles in Clark differs from the purpose of the present invention, thereby negating proper application of Clark reference. See page 4, 3rd paragraph.

Applicant's arguments have been fully considered but are not persuasive to overcome the applied rejections. Regarding Applicant's first argument, there mere physical distinction between Hess' platen and Clark's syringe does not automatically prevent their combination in teaching the present claims. Although Applicant argues that motivation is lacking, the previous Office Action provides the motivation on page 4, 1st paragraph, and this rejection is restated supra. The motivation for combining Clark's bubble-extracting step with Hess' assay method is to provides the advantages of a more precise and accurate dispensation, by removing bubbles from a fluidic system. In response to Applicant's assertion that (1) Hess does not describe bubble formation and (2) the systems of Hess and Clark are different since Hess applies "pressure" and Clark uses a "syringe", as long as there is motivation to combine references and there is a reasonable expectation of success in making the combination, the combination is

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proper. The motivation requirement has already been discussed supra. Regarding the reasonable expectation of success, while Hess does not explicitly describe bubble formation, it does not follow that Hess' system would not have problems with bubbles and that Clark's bubble-removal process would not work with Hess' system. Contrary to Applicant's statement that Hess and Clark apply two different systems, "pressure" vs. "syringe", one of ordinary skill in the art at the time of the invention would recognize that the use of a syringe necessarily produces pressure. Therefore, since both Hess and Clark's systems apply pressure in a fluidics environment, one of ordinary skill in the art at the time of the invention would also recognize that Clark's bubble-removal step would apply to other pressure-based fluidics systems, including that of Hess'.

Regarding Applicant's second argument, although the purpose of removing bubbles in Clark may be different from that of the present invention, the steps to obtain the purposes are the same. Since only reciting active steps properly claims a method, any prior art teaching the same active steps, regardless of intention, would nevertheless read on the claims. Furthermore, since the steps are the same, the prior art would also necessarily produce the same intended result as the claimed invention, regardless of whether the art expressly discloses another intended purpose. The presently claimed phrase is directed towards "performing a bubble removing or dissolving process." It is maintained that Clark's teaching of "automatically flushing bubbles out of a fluidics system" recites all the elements of the claimed phrase.

In light of the rebuttals to Applicant's arguments, the previous rejections against the pending claims are still proper and are maintained.

Conclusion

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon Y. Lum
Patent Examiner
Art Unit 1641



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